BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF:	Brien E. Pierpont et al.
SERIAL NO.:	10/773,925
FOR:	ANGIOPLASTY METHOD AND MEANS FOR PERFORMING ANGIOPLASTY
FILED:	February 6, 2004
Group/A.U.:	3763
Conf. No.:	8476
Examiner:	Laura A. Bouchelle
Docket No.:	P06547US1

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

APPEAL BRIEF

This is an appeal from the final rejection of claims 1-13 dated June 30, 2008.

I. Real Party In Interest:

The real party in interest of the instant appeal is Pierpont Family Limited Partnership, a Colorado corporation, having offices at 2028 Brightwaters Boulevard, St. Petersburg, Florid 33704 USA and Medtronic Vascular, Inc., a Delaware corporation, having offices at 3576 Unocal Place, Santa Rosa, California 95403.

Certificate of Electronic Transmission

I hereby certify that this correspondence is being transmitted to the United States Patent and Trademark Office via EFS-Web (United States Patent and Trademark Office's web-based patent application and document submission) on this 28th day of August 2008.

Timothy J. Zarley

II. Related Appeals and Interferences:

There are no related appeals or interferences.

III. Status of the Claims:

Presently, claims 1-18 are pending in the present application. Claims 14-18 were withdrawn from consideration in response to a restriction requirement. Claims 1-13 appear in Appendix A of this brief and are identified as the appealed claims.

IV. Status of Amendments:

Since the final rejection of June 30, 2008 no amendments have been filed.

V. Summary of Claimed Subject Matter:

Independent claim 1 is directed toward a catheter assembly 10 having an elongated hollow anchoring catheter 28 having a distal end, proximal end, and a tubular wall 30 with inner and outer surfaces. ([0020]). The catheter assembly 10 also has a hollow guiding catheter 50 having a distal end and a proximal end housing the anchoring catheter 28. ([0021]). A first anchoring balloon member 44 is attached to the outer surface of said tubular wall 30 of the anchoring catheter 28 and is adapted upon inflation to project outwardly from said tubular wall 30 to engage the guiding catheter 50 and secure said anchoring catheter 28 within said guiding catheter 50. ([0021, 0023]). The catheter assembly 10 also has an elongated treatment catheter 18 extending through an opening 32 in the tubular wall 30 of anchoring catheter 28 and having a distal end. ([0025]). A guide wire 16 extends through the treatment catheter 18 wherein the treatment catheter is slidable on the guide wire 16. ([0025]).

Independent claim 9 also requires a catheter assembly 10 wherein the hollow anchoring catheter 28 is extendible through guiding catheter 50. ([0025]). A treatment catheter 18 is then extended through an opening 32 in a tubular wall 30 of the anchoring catheter 28. ([0025]). An external balloon 44 that is attached to the anchoring catheter 28 is adapted to expand radially outwardly upon inflation to engage a blood vessel wall and fix the anchoring during catheter 28 against movement relevant to the blood vessel. ([0021, 0023]).

VI. Grounds of Rejection to be Reviewed on Appeal:

Claims 1-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierpont (USPN 5,484,412) in view of Crittenden et al. (USPN 4,988,356).

VII. Argument:

Rejection under 35 U.S.C. § 103, Claims 1-13.

Claims 1-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierpont in view of Crittenden. Appellant first asserts that a *prima facie* case of obviousness is not provided because a combination of the prior art references would not result in the invention as claimed in independent claims 1 and 9. Independent claim 1 requires in part "an elongated treatment catheter extending through an opening in said tubular wall of said anchoring catheter and having a distal end". Similarly amended claim 9 in part requires "a treatment catheter extending through an opening in the tubular wall of the anchoring catheter". As recognized by the Examiner, Pierpont fails to disclose a treatment catheter that extends through an opening in the tubular wall of the anchoring catheter. (Office Action, page

3). As a result the Examiner uses Crittenden to cure Pierpont.

Crittenden does not cure Pierpont as Crittenden does not teach an elongated treatment catheter extending through an opening in a tubular wall of an anchoring catheter. Instead Crittenden teaches a guide wire 14 that extends through a slit 28 of a catheter 10. (Col. 4, lines 57, through Col. 5, line 9). Specifically catheter 10 is a balloon dilatation catheter used in angioplasty procedures. (Col. 4, lines 38-42). Additionally this catheter 10 is formed with the longitudinal slit 28. (Col. 4, lines 57-62). Thus Crittenden does not teach a treatment catheter 10 extending through an opening in another catheter and instead teaches a guide wire extending through an opening in a treatment catheter. Therefore each and every limitation of claims 1 and 9 would not result from a combination of the references and a *prima facie* case of obviousness has not been presented. Consequently Appellant asserts the obviousness rejection should be withdrawn.

Appellant additionally asserts claims 1 and 9 are non-obvious because there would be no reason to combine the Pierpont and Crittenden references. The Supreme Court recently warned against rigid and preventative rules in regard to teaching, suggestion and motivation to combine that may deny the use of common sense. (See KSR Int'l Company v. Teleflex, Inc., 127 S.Ct. 1727, 82 U.S.P.Q. 2d, 1385 (2007)). Still a fact finder should be aware of the distortion caused by hindsight bias and arguments relying on *ex post facto* reasoning. Id. "Rejections on obvious grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpining

to support the legal conclusion of obviousness." Id. (Quoting In re Kahn, 441 F.3rd 977, 988) (Fed.Cir. 2006)).

Appellant asserts that upon review of the prior art references there is neither an explicit or inherent reason for combining the references. Specifically the Pierpont reference is directed toward improving the advancement of the balloon dilatation catheter. (Pierpont, Col. 1, line 62 through Col. 2, line 5). Crittenden is not concerned with the advancement of a balloon dilatation catheter. Instead Crittenden is directed towards avoiding a long exchange guide wire, exchanging guide wires within a catheter, minimizing tension load on a guide wire and minimizing the risk of guide wire entanglement in procedures when multiple guide wires are used. (Crittenden, Col. 2, line 3-16).

Thus the Pierpont reference solves the problem of advancing a balloon dilatation treatment catheter whereas the Crittenden reference solves problems associated with guide wires. Therefore, Appellant asserts that at the time the invention was made that Pierpont as one skilled in the art would not have a reason to consider the Crittenden reference as Pierpont was not interested in solving problems associated with a guide wire. Similarly, at the time the invention was made Crittenden as one skilled in the art did not have a reason to improve advancement of a balloon dilatation catheter as Crittenden was not interested in problems regarding the advancement of a balloon dilatation treatment catheter. Thus Appellant asserts that there is not an explicit reason within the Pierpont or Crittenden references that would cause one skilled in the art to combine the references to arrive at the claimed invention.

Additionally, Appellant asserts there are not inherent teachings within the references or within the skill of the

art that would provide a reason to combine the guide wire improvement of Crittenden with the treatment catheter improvement of Pierpont. Specifically, Pierpont's solution added extra structural support to the balloon dilatation treatment catheter. (See Pierpont Col. 1 line 51 - Col. 2 line 11 and Col. 3 lines 33-40). In contrast the solution of Crittenden inherently weakens the balloon dilatation catheter structure 10 while by placing a slit 28 therein. (See Crittenden (Col. 4 lines 57-62). Thus the inherent teachings of the references would not cause one skilled in the art to combine the references to arrive at the claimed invention.

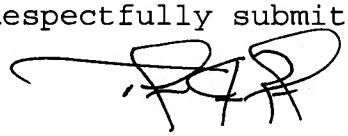
Consequently there is not an explicit or inherent reason for combining the references and Appellant asserts the combination is not obvious. Therefore Appellant respectfully requests allowance of the claims.

As additional evidence that the combination of the Pierpont and Crittenden references are non obvious Appellant points to the fact that Dr. Pierpont, one of the named inventors of the present application, was the inventor of the Pierpont reference. Dr. Pierpont has worked in the angioplasty field for many years and has received patent protection for his work. In sum, Appellant asserts that the inventor is someone of not just ordinary skill in the art but advanced skill in the art. The Crittenden reference that has been in the art since 1991 and is well known to Dr. Pierpont as Pierpont and Crittenden worked together at Medtronics Vascular, Inc. for several years. Yet at the time Dr. Pierpont filed his original '412 application that is now being cited against him, and while working with Crittenden Dr. Pierpont did not contemplate using Crittenden's teachings. Not until several years later when this application was filed in 2004, did Dr. Pierpont along with

the other inventor contemplate using Crittenden's teachings and determined how they could be implemented on Dr. Pierpont's original device. When considering that Dr. Pierpont is one of advanced skill in the art and had fully considered the teachings of the prior art references cited without combining them for several years Appellant asserts this is extremely strong evidence that the combination of these two references is not obvious to one of ordinary skill in the art. For this reason and for the other reasons stated above Appellant respectfully requests that the findings of the final office action be reversed. Additionally, claims 2-8 depend on claim 1 and claims 10-13 depend on claim 9 and for at least this reason Appellant also considers them in allowable form. As a result, Appellant respectfully requests reversal of all claims of the final office action.

A check in the amount of $510.00 has been included with this appeal brief. All fees or extensions of time believed to be due in connection with this response are attached hereto; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account 50-2098.

Respectfully submitted,



Timothy J. Zarley
Reg. No. 45,253
ZARLEY LAW FIRM, P.L.C
Capital Square
400 Locust Street, Suite 200
Des Moines, IA 50309-2350
Phone No. (515) 558-0200
Fax No. (515) 558-7790
Customer No. 34082
Attorneys of Record

TJZ/JLH/bjs
Attachment: Appendix

APPENDIX A

VIII. Claims Appendix

1. A catheter assembly, comprising,
an elongated hollow anchoring catheter having a distal end, a proximal end and a tubular wall with inner and outer surfaces,
a hollow guiding catheter having a distal end and a proximal end housing said anchoring catheter,
a first anchoring balloon member attached to the outer surface of said tubular wall of the anchoring catheter and adapted upon inflation to project outwardly from said tubular wall to engage the guiding catheter and secure said anchoring catheter within said guiding catheter,
an elongated treatment catheter extending through an opening in said tubular wall of said anchoring catheter and having a distal end, and
a guide wire extending through the treatment catheter and along which the treatment catheter is slidable.

2. The assembly of claim 1 wherein the opening in the tubular wall of the anchoring catheter is a slit extending between the distal end and the proximal end of the anchoring catheter.

3. The assembly of claim 2 wherein a guide member is slidably mounted on the anchoring catheter and facilitates the insertion of the balloon dilatation catheter through the slit.

4. The assembly of claim 2 wherein the slit has a means for releasably sealing the slit.

5. The assembly of claim 1 further comprising a second anchoring balloon member attached to the inner surface of said tubular wall and adapted upon inflation to project inwardly from said tubular wall of the anchoring catheter to engage and retain the treatment catheter against movement with respect to said anchoring catheter.

6. The assembly of claim 5 further comprising a means associated with the catheter assembly for independently inflating and deflating the first and second anchoring balloon members.

7. The assembly of claim 1 further comprising a third anchoring balloon member attached to the outer surface of the tubular wall of the anchoring catheter and adapted upon inflation to project outwardly to engage the blood vessel and secure the anchoring catheter to the blood vessel, and whereby upon inflation of the first and third balloon members the guiding catheter is operatively secured to the blood vessel.

8. The assembly of claim 7 wherein blood by-pass means are located in said tubular wall on opposite sides of at least one of said first or third anchoring balloon members.

9. A catheter assembly, comprising:

a hollow anchoring catheter extendible through a guiding catheter;

a treatment catheter extending through an opening in the tubular wall of the anchoring catheter; and

an external balloon attached to the anchoring catheter and adapted to expand radially outwardly upon inflation to engage the blood vessel wall and fix the anchoring catheter against movement relative to the blood vessel.

10. The catheter assembly of claim 9 further comprising an internal balloon attached to the anchoring catheter adapted to expand radially inwardly upon inflation to engage the treatment catheter and fix the anchoring catheter against movement relative to the dilatation catheter.

11. The assembly of claim 9 wherein the opening in the tubular wall of the anchoring catheter is a slit extending between a distal end and a proximal end of the anchoring catheter.

12. The assembly of claim 11 wherein a guide member is slidably mounted on the anchoring catheter and facilitates the insertion of the balloon dilatation catheter through the slit.

13. The assembly of claim 11 wherein the slit has a means for releasably sealing the slit.

IX. Evidence Appendix

None

X. Related Proceedings Appendix

None